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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,015	11/01/2001	Michael Gerard Kelly	AM100053	3339

25291 7590 05/28/2003

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EXAMINER

HABTE, KAHSAY

ART UNIT PAPER NUMBER

1624

8

DATE MAILED: 05/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

**Office Action Summary**

Application No.

10/003,015

Applicant(s)

KELLY ET AL.

Examiner

Kahsay Habte, Ph. D.

Art Unit

1624

**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 May 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-7,9,10,12 and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-6,9,12 and 14-23 is/are allowed.
- 6) ☒ Claim(s) 7 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Claims 1, 3-7, 9-10, 12, and 14-23 are pending.

***Response to Amendment***

2. Applicant's amendment filed 05/06/03 in response to the previous Office Action (Paper No. 6) is acknowledged. Rejections of claims 1-18 under 35 U.S.C. § 112, second paragraph (Paper No. 6, paragraphs 7a-7c) have been obviated. In regard to the enablement rejections, applicants have overcome the rejection of claims 10-11 (Paper No. 6, item 5) but the enablement rejection in item 4 (Paper No.6) has been maintained.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of schizophrenia and depression, does not reasonably provide enablement for the treatment of cognitive disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There has been recited in claim 10 a method for the treatment of a disorder of the central nervous system (CNS) related to or affected by the 5-HT6

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receptors wherein said disorder is a cognitive disorder, but the specification is not enabled for cognitive disorder. See Paper No. 9 (item 4 for details)

### ***Response to arguments***

Applicants' arguments filed 05/06/2003 have been fully considered but they are not persuasive.

Applicants argue by providing three references: (A) Behavioral Brain Research, 118 92001), 107-110; (B) Expert Opinion Therapeutic Patents (2002) 12 (4), 513-527; and (C) Current Opinion in Investigational Drugs, (2001) 2(1), 118-122. Applicants indicate that the modulation of the 5-HT<sub>6</sub> receptors site is clearly linked to the treatment of cognitive dysfunction (A, p. 109; B, p.525 and C, p. 120).

In regard to reference A, it was noted on page 109 (4. discussion) "The major finding of the present study was that, post-training injection of the 5-HT<sub>6</sub> receptor antagonist Ro 04-6790 alone enhanced learning consolidation. While, ritanserin or WAY 100635 had no effect." This indicates that not all 5-HT<sub>6</sub> receptors antagonists are associated with cognitive disorder, because a 5-HT<sub>6</sub> antagonist "ritanserin" had no effect. Further, note that this just covers "learning consolidation," which is just one of many, many, aspects of cognitive disorder.

In regard to B, the examiner points out a statement on page 525 (4. Expert opinion) that says "Based on aforementioned evidence, it is now becoming clear that targeting the 5-HT<sub>6</sub> receptor with selective antagonists is a viable drug development strategy, since novel drugs with potential for treating a large number of common

disorders, including schizophrenia, and cognitive dysfunction, are possible.” This indicates that the treatment of cognitive disorders is suggested as a possibility. It is just an opinion that selective antagonists of 5-HT<sub>6</sub> receptors may be useful in treating cognitive dysfunctions. There is no suggestion that the treatment is actually done. The fact that it is only called a “strategy” means that it is not enabled for such a scope.

In regard to Reference C, this describes very early work on SB-271046. This indicates that the study is at its early stage. Indeed, no reports have appeared on successful treatment with SB-271046. In references A, B, and C, there is no support that indicates that “cognitive disorders” can be treated generally by compounds that inhibit 5-HT<sub>6</sub> receptors. For examples, there is no mention of treating autism or mental retardation that are cognitive disorders.

Applicants indicate that compounds of formula (I):

- a. demonstrate a high affinity for the 5-HT<sub>6</sub> and also applicants
- b. 77% demonstrated equal to or greater than the 5-HT<sub>6</sub> binding affinity of the known pharmaceutical compounds used as test standards
- c. have a known affinity for the 5-HT<sub>6</sub> receptor and have been indicated for use in the treatment of CNS diseases such as Parkinson's disease, schizophrenia, migraine, depression and psychosis.

The argument in a – c are not relevant, since the examiner is not arguing about the affinity of the compounds of formula (I) compounds to the 5-HT<sub>6</sub> receptors and the use of said compounds in the treatment of diseases such as schizophrenia, migraine,

depression and psychosis. Applicants did not address the issue (i.e. whether or not the method of treating cognitive disorders in general is enabled).

Applicants are invited to show support that cognitive disorders in general can be treated by inhibiting 5-HT<sub>6</sub> receptors.

4. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There has been recited a method of treating Parkinson's disease, but the treatment of Parkinson's disease is not enabled.

Parkinson's disease is a neurological disorder that is also characterized by rhythmic muscle tremors, hypokinesia, and muscular rigidity. Dopamine, a hormonelike substance is an important neurotransmitter in both the central and peripheral nervous systems that is currently used as treatment for Parkinsonism. Dopamine is a neurotransmitter involved in the regulation of the central nervous system. The skill level in the art is such low that the only treatments available to this day are drugs that are helpful in regulating Dopamine. Thus, a rejection under 35 U.S.C. 112, first paragraph is proper.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 10, the phrase "Parkinson's disease" is not cognitive disorder.

### ***Conclusion***

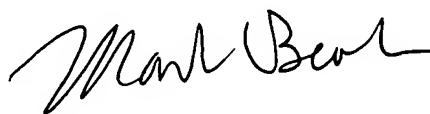
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Kahsay Habte, Ph. D.  
Examiner  
Art Unit 1624



Mark L. Berch  
Primary Examiner  
Art Unit 1624

KH  
May 27, 2003